



Chocolate Manufacturers Association • National Confectioners Association

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 99N-2497: Citizen Petitions; Actions That Can be
Requested by Petition; Denials, Withdrawals, and Referrals
for Other Administrative Action

Dear Sir or Madam:

The Chocolate Manufacturers Association (CMA) and the National Confectioners Association (NCA) are pleased to submit these comments on the Food and Drug Administration's (FDA) proposed rule amending its citizen petition regulation.

CMA is the national, not-for-profit trade association representing the majority of chocolate manufacturers in the United States. CMA members produce over 90 percent of all chocolate manufactured in this country. In addition to supplying the trade with bulk chocolate products, CMA members also manufacture and market a wide variety of finished chocolate and chocolate-containing confectionary products for the consumer market. NCA is the national, not-for-profit trade association representing confectionary manufacturers and suppliers.

CMA and NCA appreciate the FDA's resource constraints and the agency's need to both limit the volume of citizen petitions it receives and expedite the citizen petition review process. However, we believe that the proposed rule as drafted would authorize FDA to indefinitely postpone action on citizen petitions that relate to commercial, as opposed to food safety or nutritional, issues. This would be inconsistent with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's responsibility to regulate all aspects of food. In addition, although this may not be the FDA's intent, it sets the stage for the curtailment of innovation in the food industry.

Proposed § 10.30(e)(2)(ii) provides that FDA's denial of a citizen petition may be "brief, as appropriate." The preamble explains that such a brief denial would be appropriate in the case

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of a citizen petition that “does not implicate a significant public health issue” and the agency lacks the resources to provide a more detailed response.

.... This may occur, for example, where the petitioner requests a change in FDA’s regulations that has no significant public health implications, such as amending or establishing common or usual names regulations or standards of identity, quantity, and fill of container regulations for foods.... In the absence of a significant public health issue, and considering the intense demand on FDA’s resources, the agency must allocate its resources carefully and wisely, so brief denial of these types of citizen petitions would be appropriate.

64 *Federal Register* 66822, 66824-5 (Nov. 30, 1999).

Similarly, proposed § 10.30(e)(4)(i)(D) authorizes FDA to refer a citizen petition “for other administrative action instead of issuing a response.... and close the docket for the petition” if the petition “[d]oes not involve a significant public health or consumer protection issue.”

These provisions would grant FDA authority to summarily dismiss, or indefinitely postpone action on, a citizen petition to amend or establish a common or usual name regulation or standard of identity. Submitting a citizen petition to amend a standard of identity is often the only means a manufacturer has to market a new form of a product covered by a standard of identity. As FDA recognized in the preamble language quoted above, petitions to amend a standard of identity do not have public health implications. Thus, the proposed rule would render ineffective an important mechanism used by food manufacturers to improve their products and to respond to changing marketplace needs.

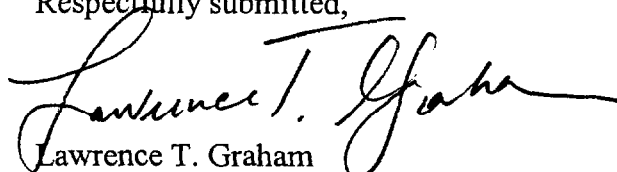
FDA could also use these provisions of the proposed rule to reject requests for temporary marketing permits (TMPs). Manufacturers use TMPs to test new products that deviate from an applicable standard of identity. FDA will only issue a TMP in order to test market a product for the purpose of ultimately amending the relevant standard of identity. Under the proposed rule, FDA could deny a TMP on the grounds that the citizen petition that would result from the TMP would not have public health implications.

Standards of identity and TMPs are of crucial importance to the chocolate and confectionary industries, as a great number of our products are, or contain, foods subject to the cacao standards in 21 C.F.R. Part 163. We have a long history of interest in the cacao standards. For example, the standards were revised and “modernized” in 1993 in response to a CMA citizen petition. Also in 1993, we submitted a citizen petition to adopt a standard of identity for white chocolate, based on the marketing experience of a number of member firms under TMPs. In 1997, FDA proposed to adopt a white chocolate standard. We hope that FDA will proceed to publish a final white chocolate standard in the very near future. This history shows that standards of identity are a subject of real concern to our members. Citizen petitions to amend or adopt standards of identity should be considered on their merits, not summarily rejected or held in abeyance for procedural reasons.

Accordingly, CMA and NCA request that proposed § 10.30(e)(4)(i)(D) and the preamble language quoted above relating to proposed § 10.30(e)(2)(ii) be removed in their entirety from any final rule based on the proposal. If these provisions are retained, CMA and NCA fear that they may ultimately have the effect of stifling innovation in the food industry and denying food manufacturers an important mechanism for improving their products.

We appreciate this opportunity to comment on the proposed rule.

Respectfully submitted,


Lawrence T. Graham
President